REMARKS

Status of the Claims

Claims 26-34 and 61-62 are currently pending.

Claim 26 is currently objected to based upon the use of "comprise" on lines 5-6. Claim 26 has been amended to recite "wherein said assembled bone graft does not include an adhesive." This amendment does not add new matter. Applicants believe that this amendment is grammatical in nature and does not change the scope of claim 26. Applicants believe that this amendment to claim 26 overcomes the currently pending objection. Claim 26 has also been amended to recite pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft. This amendment does not add new matter.

Claims 27 and 34 have also been amended to recite pins comprising cortical bone. These amendments to not add new matter.

Claim 28 is currently objected to based upon the use of the term "("cortical bone pins")." Claim 28 has been amended to remove the parenthetical, and to recite, "An assembled bone graft suitable for implantation in a human patient comprising two or more distinct bone portions of machined allograft bone and pins comprising cortical bone, said two or more distinct bone portions having holes therein for receiving said pins, said pins keeping said two or more distinct bone portions aligned and connected to form said assembled bone graft free of an adhesive and suitable for implantation in a human." This amendment does not add new matter. Applicants believe that this amendment is grammatical in nature and does not change the scope of claim 28. Applicants believe that this amendment to claim 28 overcomes the currently pending objection.

Claims 29 and 30 have been amended to remove unnecessary commas between the words "distinct" and "bone." These amendments are grammatical in nature and do not alter the scope of the claims or add new matter to the claims.

Claims 26 and 33 are currently provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 79 of co-pending Application Serial No. 09/941,154. Applicants note this provisional rejection, and will take appropriate action if this rejection should ripen.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pat. No. 5,147,367 (the "Ellis" reference). Applicants respectfully traverse this rejection for the reasons stated in section I below.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the Ellis reference. Applicants respectfully traverse this rejection for the reasons stated in section II below.

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Pat. No. 5,716,358 (the "Ochoa" reference) in view of the Ellis reference. Applicants respectfully traverse this rejection for the reasons stated in section III below.

Claims 26-34 and 61-62 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0517030 (the "Siebels" reference) in view of U.S. Pat. No. 5,989,289 (the "Coates" reference). Applicants respectfully traverse this rejection for the reasons stated in section IV below.

I. 35 U.S.C. § 102(B) OVER THE ELLIS REFERENCE

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the Ellis reference (U.S. Pat. No. 5,147,367). With regard to the anticipation rejections, the MPEP provides:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

MPEP §2131 (emphasis added). Applicants respectfully traverse the current rejections under 35 U.S.C. §102(b) because the Ellis reference does not disclose each and every element of claims 26-27 and 31-34 of the instant application.

A. Ellis does not disclose a "graft" as the term is understood in the art

Claims 26-27 and 31-34 are each directed to an "assembled bone graft." The Ellis reference does not teach a "graft" as the term is understood in the art. Tellingly, the Ellis

reference does not use the term "graft." Instead, the Ellis reference states that it relates to "fixation of bone fractures," (Ellis at Abstract), and the "setting of bone fragments relative to the adjacent bone mass." (Ellis at Col. 1, lines 6-8). The Ellis reference further describes this process as being a "repair." (Ellis at Col. 3, line 18; Col. 3, lines 41-42; Col. 5, line 13; and Col. 5, line 50). Figures 2a-2d and 3-5 of the Ellis reference further illustrate that Ellis relates to the fixation of bone fractures wherein a broken bone is re-attached to the same site from which it was fractured. (See Ellis at Figures 2a-2d and 3-5; see also Ellis at Col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condoyle 201 and an adjacent underlying bone mass 202.").)

In making the assertion that Ellis relates to "grafts," the Office Action disregards the teachings of Ellis as relating to bone repairs. Instead, the Office Action attempts to read "graft" into the Ellis reference by asserting that Ellis discloses a "graft" when the term "graft" is given its "broadest reasonable interpretation." See the October 25, 2006 Office Action at p. 4. In support of the interpretation of the term "graft," the October 25, 2006 Office Action cites to Stedman's Medical Dictionary, 23rd Edition, p. 599, for the definition of "graft" as being "anything inserted into something else so as to become an integral part of the latter." See the October 25, 2006 Office Action at p. 4 (emphasis added). As discussed above, however, the Ellis reference relates to the fixation of bone fractures wherein a broken bone is re-attached to the same site from which it was fractured. The October 25, 2006 Office Action admits that Ellis discloses "bone portions of the same patient" being bound back "onto the bones they were separated from." See the October 25, 2006 Office Action at p. 3. This does not fit the definition of a graft as set forth in Stedman's Medical Dictionary, 23rd Edition, at p. 599, because the bone fragments of Ellis are not being "inserted into something else."

Additionally, given the recognitions in the October 25, 2006 Office Action that Ellis discloses "bone portions of the same patient" being bound back "onto the bones they were separated from," see the October 25, 2006 Office Action at p. 3, the definition in Stedman's Medical Dictionary, 23rd Edition, at p. 599 of "autogenous bone graft" as being "a bone g[raft] from one part of the body to another" is particularly notable. In accordance with this definition, in order for a bone portion from a patient to be a "graft" with respect to that same patient, it would have to be taken from one part of the body and be put into another. The specification of the instant application is in accordance with this definition in referring

to autograft materials. See specification at p. 1, line 30 to p. 2, line 1 ("a second site of morbidity must be created to harvest autograft for implantation into a first diseased or injured site").

The interpretation in the Octiober 25, 2006 Office Action of a "graft" as including bone being re-attached to the site from which it was originally fractured is thus inconsistent with the term "graft" as used in the art, as evidenced by the fact that it is inconsistent with the definition in Stedman's Medical Dictionary, 23rd Edition, at p. 599 that has been provided in the October 25, 2006 Office Action. "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." MPEP §2111.

B. Ellis Does Not Disclose An "Assembled Bone Graft"

Claims 26-27 and 31-34 are each directed to an "assembled bone graft." The Ellis reference does not disclose an assembled bone graft as recited in any of these claims. As discussed above, the Ellis reference does not disclose a "graft." Additionally, each of claims 26-27 and 31-34 recites elements relating to the "assembled bone graft" recited therein that are not met by the Ellis reference.

Claim 26 recites, among other things, that the assembled bone graft comprises "a plurality of machined allograft bone portions layered to form a graft unit, and biocompatible pins traversing said graft unit for holding said graft unit together as an assembled bone graft." Claim 26 also recites that the assembled bone graft is "assembled outside the body and suitable for implantation into a human patient." The Ellis reference discloses neither of these elements. For example, in the Ellis reference only a single bone portion is shown as being broken or fractured, and being subsequently fixed to the underlying bone mass. (See Ellis at Col. 2, lines 56-64; Col. 3, lines 3-5; Col. 3, lines 19-22; Col. Col. 3, lines 28-34; Col 3, lines 38-40; Col. 4, lines 16-18; Col. 4, lines 27-28; Col. 5, lines 41-42; and at Figs. 2a-2d and 3-5.) As disclosed in Ellis, the single fractured fragment is fixed to the underlying bone mass to re-form the original bone inside the body. The Ellis reference does not disclose removing the fractured or broken bone from the body. The broken or fractured bone as disclosed in Ellis thus does not exist in an "assembled"

form outside the body as an "assembled bone graft" that is "suitable for implantation into a human patient."

Similarly, claims 27 and 31-34 each require an "assembled bone graft" comprising "two distinct bone portions" (claim 27), or "a first" and "a second" bone portion (claims 31-34), that form "an assembled bone graft suitable for implantation" into a human patient. As discussed above, the Ellis reference does not disclose an assembled bone graft comprising two bone portions that are implanted into a human patient. Instead, the Ellis reference discloses a single bone being broken or fractured from the underlying bone mass, and being subsequently fixed to the underlying bone mass. (See Ellis at Col. 2, lines 56-64; Col. 3, lines 3-5; Col. 3, lines 19-22; Col. Col. 3, lines 28-34; Col 3, lines 38-40; Col. 4, lines 16-18; Col. 4, lines 27-28; Col. 5, lines 41-42; and at Figs. 2a-2d and 3-5.)

C. Ellis Does Not Disclose "Allograft" Bone

The October 25, 2006 Office Action states that "Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft in Ellis...." See the October 25, 2006 Office Action at pp. 3-4. Although applicants disagree with the characterization of the Ellis reference as relating to a "graft" at all, as discussed above, the admission that Ellis relates to "bone portions of the same patient" is an admission that the claimed element of "allograft bone" is not disclosed in Ellis.

The October 25, 2006 Office Action asserts that "[s]ince the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion...." See the October 25, 2006 Office Action at p. 4. The Ellis reference, however, does not disclose, either explicitly or inherently, that the bone disclosed therein could or should be used in another patient upon the death of the first patient. Instead, the assertion in the October 25, 2006 Office Action is based solely upon presumption, with no teaching in the art cited as support. The assertion set forth in the October 25, 2006 Office Action does not constitute a description of the claim element being set forth in the cited reference, as is required for anticipation by MPEP §2131. The Ellis reference therefore does

not anticipate the claim element of "allograft bone" as recited in each of claims 26-27 and 31-34.

The October 25, 2006 Office Action also asserts that the claim elements reciting allograft bone "merely indicate[] where the tissue is obtained and how it is intended to be used and not on any clear structural feature of the material." October 25, 2006 Office Action at pp. 7-8. Applicants respectfully disagree with this characterization of the claim element "allograft." The requirement that bone be allograft is a positively recited requirement within the body of the claim, and is not merely a statement of intended use. The claim element requiring allograft bone cannot be ignored.

D. Ellis Does Not Disclose a "Machined" Portion of Bone

Claims 26-27 and 31-34 each recite as an element that the bone portions of the assembled bone graft are "machined." As discussed above, the Ellis reference discloses repairing a bone break or fracture by reattaching a single fractured piece of bone to the "adjacent underlying bone mass" from which it originally fractured. See Ellis at Col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condoyle 201 and an adjacent underlying bone mass 202"). The Ellis reference does not disclose machining a bone portion. The claim elements in claims 26-27 and 31-34 reciting "machined" bone portions are thus not anticipated by the Ellis reference.

Because there are numerous claim elements in each of claims 26-27 and 31-34 that are not disclosed in the Ellis reference, the Ellis reference does not anticipate any of claims 26-27 or 31-34. Applicants respectfully request that the pending rejection under 35 U.S.C. §102(b) in light of the Ellis reference be withdrawn.

II. 35 U.S.C. § 103(A) IN LIGHT OF ELLIS

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the Ellis reference. In order for a prima facie case of obviousness to be established, the Manual of Patent Examining Procedure (MPEP) states:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the teaching. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.

MPEP §2142 (emphasis added). "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." See id.

Applicants respectfully submit that no prima facie case of obviousness has been established because the cited reference does not teach or suggest each of the elements of any of claims 26-27 or 31-34. Additionally, as discussed above, the Ellis reference relates to the repair of fractured or broken bones within a patient. For example, the Ellis reference does not disclose an assembled bone graft suitable for implantation into a human patient that comprises multiple bone portions. As another example, the Ellis reference also does not disclose the use of machined allograft bone portions in forming an assembled bone graft. Modification of the teachings of Ellis to arrive at such subject matter would change the principle of operation of the cited reference, which is not sufficient to render the claims prima facie obvious. See MPEP §2143.01 (citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Applicants respectfully request that the pending rejection under 35 U.S.C. §103(a) in light of the Ellis reference be withdrawn.

III. 35 U.S.C. § 103(A) OVER OCHOA IN VIEW OF ELLIS

Claims 26-27 and 31-34 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Pat. No. 5,716,358 (the "Ochoa" reference) in view of the Ellis reference. The October 25, 2006 Office Action states that "Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use

of a plurality of pins as now claimed." See October 25, 2006 Office Action at p. 5. The Office Action then cites to Ellis for the proposition that "it was known to use a plurality of pins to attach bone pieces together." See October 25, 2006 Office Action at p. 5.

The October 25, 2006 Office Action does not show the manner by which each and every element of any of the currently amended claims is allegedly met by the cited references, either alone or in combination. "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness," MPEP §2142, and part of that burden includes establishing that the prior art references teach or suggest all the claim limitations.

The Applicants respectfully submit that the cited combination of Ellis and Ochoa fails to make a *prima facie* case of obviousness against the presently claimed invention because the combination of the two references fails to disclose each and every element of the currently amended claims. The Ochoa reference is directed to a "bone fixation device such as a screw, pin, staple, cable, or anchor." See the Ochoa reference at Abstract. The Ochoa reference further states that "[t]he present invention relates to mechanical fixation devices and hardware used in surgical applications to attach or anchor bone tissue or prosthetic devices to bone, or to secure pieces of bone together." See the Ochoa reference at Col. 1, lines 4-7. Ochoa, like Ellis, does not disclose assembled bone grafts such as those recited in claims 26-26 and 31-34.

For example, each of claims 26-27 and 31-34 are directed to an "assembled bone graft" that is "suitable for implantation" in a human patient, where the assembled bone graft comprises a plurality of bone portions. The Ochoa reference discloses that the fixation device disclosed therein can be used to reconstruct broken bones within a patient by threading a plurality of bone fragments together, (see the Ochoa reference at col. 6, lines 58-60), but as indicated in the October 25, 2006 Office Action, this relates to "bone portions or pieces grafted back onto bones they were separated from." See October 25, 2006 Office Action at p. 5. Ochoa does not teach a bone graft that is assembled from multiple bone portions and then implanted into a patient, as is required by each of claims 26-27 and 31-34. Because Ellis also does not teach such assembled bone grafts, the combination of Ellis and Ochoa does not render the currently amended claims obvious.

Additionally, each of claims 26-27 and 31-34 recite that the bone portions used in the assembled grafts are machined allograft bone. Ochoa and Ellis are directed to repairing

fractured bones within a patient. Neither reference disclose either the use of machined bone portions or the use of allograft bone, much less the use of bone that is both machined and allograft.

In light of the fact that each and every limitation of the currently amended claims is not disclosed or taught by Ochoa or Ellis, Applicants respectfully request that the pending rejection under 35 U.S.C. §103(a) in light of Ochoa and Ellis withdrawn.

IV. 35 U.S.C. § 103(A) OVER SIEBELS IN VIEW OF COATES

Claims 26-34 and 61-62 are currently rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0517030 (the "Siebels" reference) in view of U.S. Pat. No. 5,989,289 (the "Coates" reference). The October 25, 2006 Office Action asserts that "Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together by aligning bones of adjacent pieces," and introducing "pins into the aligned bones to hold the implant pieces together." See the October 25, 2006 Office Action at p. 5. The October 25, 2006 Office Action admits that "Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6)." See the October 25, 2006 Office Action at p. 5. The October 25, 2006 Office Action then cites to Coates, alleging that Coates "teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61." See the October 25, 2006 Office Action at p. 6. The October 25, 2006 Office Action then concludes that "it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same." See the October 25, 2006 Office Action at p. 6. The Applicants respectfully traverse this rejection, and submit that it would not have been obvious to one of ordinary skill in the art to combine the teachings of Siebels and Coates to arrive at the currently claimed subject matter.

A person of ordinary skill in the art would not have combined the teachings of Siebels and Coates because they relate to different approaches to making implants. There would not be a reasonable expectation of success in making the combination proposed by

the October 25, 2006 Office Action. An obviousness rejection must include "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, (Federal Circuit 2006.

When the substance and teachings of the Siebels reference and the Coates reference are properly considered, it is clear that one of ordinary skill in the art would not be motivated to combine the two references by replacing the artificial materials used in Siebels with the cortical bone used in the implants of Coates. It is not permissible to pick and choose among the individual elements of assorted prior art references to re-create the claimed invention, but rather "some teaching or suggestion in the references to support their use in the particular claimed combination" is needed. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1576, 19 USPQ2d 1241, 1246 (Fed. Cir. 1991). Furthermore, prior art references must be considered in their entirety, "i.e., as a whole, including portions that would lead away from the claimed invention." MPEP at § 2141.02. (Emphasis added.)

A. A Person of Ordinary Skill in the Art Would Not Have Modified Siebels to Substitute Bone for Plastic

The Siebels reference describes the basis of the invention described therein in the following manner:

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which – from the standpoint of manufacturing engineering – can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

See Siebels translation at p. 2. Ease of manufacturing and ease of implantation are central aspects of the Siebels implant, and serve as the solutions for the nature of the problem addressed by Siebels. To achieve the aspect of "ease" of manufacturing, Siebels relies upon cutting disks out of a "prefabricated solid or hollow strand." See Siebels translation at p. 3.

The only materials actually described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are "fiber reinforced plastic," see Siebels translation at p. 3, and "carbon-fiber reinforced plastic." See Siebels translation at

p. 6. The Siebels reference does not describe any other materials from which its implants or anchoring pins can be made.

With respect to the anchoring pins disclosed in the Siebels reference, there is no discussion, aside from the one reference to carbon-fiber reinforced plastic on page 6, of suitable materials from which they can be made. Nor is there any discussion of the parameters or factors that should be considered when choosing the material from which to make the anchoring pins. There is thus no teaching within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

With respect to the disks used for the implants described in the Siebels reference, the manufacturing methods by which the implants of Siebels can "easily be manufactured" in accordance with the "basis of the [proposed] invention," see Siebels translation at p. 2, make it evident that the only suitable materials are the plastics described therein. For example, the manufacturing techniques of Siebels are described in the following manner:

> Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.
>
> Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

Siebels translation at pp. 6-7 (emphasis added). Additionally, the Siebels reference describes one embodiment by explaining that:

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in

> order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having a rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

Siebels translation at pp. 3-4 (emphasis added). Furthermore, Figures 5 and 6 of the Siebels reference provide illustrations of the manufacturing of the winding methods described in Siebels and the disks cut therefrom. The structure and shape of the disks described by Siebels are dictated by the braided or wound stands from which they are cut, and even the strength and rigidity of the disks is a result of the oriented fibers that result from the manufacturing techniques. The manufacturing methods taught in the Siebels reference that achieve the described advantages may be suitable for use with the plastics described in Siebels, but they could not be performed on cortical bone.

The Siebels reference, when read as a whole, is directed to providing implants and implant components that can be easily manufactured. The Siebels reference thus teaches away from the use of materials or manufacturing techniques that do not provide the benefit of easy manufacturing as described within the Siebeles reference. There is no teaching or suggestion in Siebels that the manufacturing techniques could be altered or disregarded in making the disks taught therein.

The MPEP explains that "[a] prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness." MPEP §2145(X)(D)(1). Further, "[a] prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant." Monarch Knitting v. Sulzer, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998). In reading the Siebels reference, one of ordinary skill would be led towards the ease of manufacturing obtained by using the plastics and manufacturing methods described in Siebels and would therefore be led in a divergent

direction from developing different manufacturing techniques to allow the use of bone as a manufacturing material.

B. Coates Does Not Teach that Bone Can Be Substituted For The Materials of Siebels

The Coates reference, when considered as a whole, does not teach that cortical bone could be used in the implants of Siebels.

As an initial matter, the implants disclosed in the Coates reference differ from the implants and portions of implants claimed in the present application in several respects. As described in Coates, "[t]he spacer 110 includes an anterior wall 111 having opposite ends 112, 113, a posterior wall 115 having opposite ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone." See Coates at Col. 5, ln 66 to Col. 6, ln 5. In contrast to the assembled bone grafts recited in claims 26-34 and 61-62, the Coates reference does not describe bone grafts made from multiple pieces of cortical bone, nor does it describe connecting multiple pieces of bone using pins made from cortical bone.

Coates seeks to develop implants made of bone that "avoid the disadvantages of metal implants." See Coates at Col. 2, lns 50-51. In describing the benefits of its implants, the Coates reference states:

> One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of metals, without the corresponding disadvantages. An additional benefit is that the invention provides a stable scaffold for bone ingrowth before fusion occurs. Still another benefit of this invention is that it allows the use of bone grafts without the need for metal cages or internal fixation, due to the compressive strength of the spacer and the means for resisting migration.

See Coates at Col. 4, lns 8-16. (Emphasis added).

Notably, the Coates reference does not discuss plastic implants, or the advantages or disadvantages thereof as compared to either metal or bone implants. The Coates reference does not provide any teaching with respect to the possibility or desirability of

substituting the use of bone in other grafts, such as those of the Siebels reference, that are made from plastic. With respect to materials and manufacturing methods, the Coates reference provides the following description:

> The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape. Material from the medullary canal of the ring can be removed to form a chamber. Surface features and migration resistance means can be defined into the surface of the spacers using conventional machining methods and a standard milling machine which have been adapted to bone. Various methods and procedures are known for treating and processing bone to provide bone materials and compositions. These methods and procedures can be applied to the present invention as long as the resulting bone material provides a sufficient compressive strength for the intended application.

See Coates at Col. 11, lns 42-60. (Emphasis added). Thus, the known methods of manufacturing described in Coates require modifications in order to adapt the equipment for use with bone. Further, in the Background section provided therein, the Coates reference discusses some of the disadvantages and difficulties that were known with respect to making implants from bone:

> Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the graft/fusion-site interface may disrupt the healing process that is required for fusion.
>
> Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the

> biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.

See Coates at Col. 3, lns 17-40. (Emphasis added). Thus, it was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. And, although the Coates reference goes on to describe its single piece bone implants as providing one solution to the difficulties associated with using bone implants, the Coates reference when read as a whole does not provide a teaching that bone can simply be substituted as a manufacturing material in any type of implant.

In light of the disclosures of the Siebels reference and the Coates reference when read in their entirety, one of ordinary skill in the art would not combine the Siebels reference and the Coates reference to arrive at implants or portions of implants made from multiple pieces of cortical bone connected by cortical bone pins as disclosed and claimed in the present application. "A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." In re Kotzab, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); see also In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). When this critical step is taken with respect to the Siebels reference and the Coates reference, it becomes apparent that given the "extremely difficult or impossible" setting of developing an implant from cortical bone as described in the Coates reference, one skilled in the art would not have substituted cortical bone of Coates for the "extraordinarily easy" to use braided or wound plastics of Siebels. The teachings of Coates thus fail to address or overcome the stated manufacturing advantages associated with the fiber reinforced plastic of Siebels, so one of ordinary skill in the art would not have disregarded the ease of manufacturing advantages associated with the plastics of Siebels in choosing the materials for making either the primary components of an implant or the pins used to hold the implant together. Moreover, given the art recognized extreme difficulty or impossibility of developing an implant made from a single piece of cortical bone as disclosed in Coates, it would not have been obvious to one of ordinary skill in the

art to further modify the implants of Coates by building an implant assembled from pieces of cortical bone held together with pins.

C. There is No Reasonable Expectation of Success in Combining Siebels and Coates

The October 25, 2006 Office Action does not provide any basis for a reasonable expectation of success for using cortical bone to manufacture implants and portions of implants made from multiple pieces held in juxtaposition by cortical bone pins, as described and claimed in the present application. When addressing the issue of a reasonable expectation of success, the MPEP explains, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required." MPEP §2143.02. The MPEP further states, "Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made." MPEP §2143.02. When the cited prior art references are viewed in this context, it becomes apparent that they do not provide a reasonable expectation of success with respect to substituting cortical bone as a manufacturing material into the implant pieces of the Siebels reference. For example, given the difficulties with making bone grafts as described in the Coates reference, there would not have been a reasonable expectation of success that implants could be assembled from multiple pieces of cortical bone. The Coates reference is directed to a single piece implant and does not address the utilization of multiple pieces.

Further, both the Coates reference and the Siebels reference discuss the need for implant strength, but neither addresses whether multiple cortical bone pieces held in juxtaposition would provide such strength. To the contrary, the Coates reference expresses the concern that "[g]raft alone may not provide the stability required to withstand spinal loads," see Coates at Col. 3, lns 18-19, and then states that "the spacers of this invention stimulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft and metal implants...." See Coates at Col. 5, lns 21-24 (Emphasis added). Similarly, the Siebels reference describes that the fiber reinforced plastic implants disclosed therein "are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation

equally imparts an optimal rigidity and strength to the implant." See Siebels translation at p. 3 (emphasis added). Thus, while the Coates and Siebels references each describe that their own implants provide the necessary strength, neither one provides a basis from which it could be concluded that cortical bone pieces held in juxtaposition by cortical bone pins would successfully provide sufficient strength.

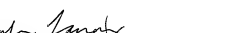
Because the combination of references in the pending obviousness rejection is not based upon any reasonable expectation of success found in the prior art, a prima facie case of obviousness has not been made and the rejection should be withdrawn.

Conclusion

Claims 26-34 and 61-62 are currently pending. The specification currently stands objected. Claims 26-34 and 61-62 currently stand rejected. In view of the amendments and arguments provided herein, Applicants believe that all bases for objecting to and rejecting claims 26-34 and 61-62 have been overcome. Applicants respectfully submit that Claims 26-34 and 61-62 of the instant application are in a condition for allowance.

Applicants believe that a total fee of $910 is currently due in conjunction with submission, with $790 for the Request for Continued Examination and $120 for the One Month Petition for Extension of Time that are being submitted with this Amendment and Response. The Commissioner is hereby further authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

Date: February 26, 2007 By: 

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